

CONFIDENTIAL

Application No. 09/702226

Filed: October 31, 2000

Inventor: Walak

- 22 -

What is claimed:

- 1 1. An endoluminal device comprising at least one superelastic section and
2 at least one plastically deformable section.
- 1 2. The device of claim 1, wherein the plastically deformable section has a
2 greater x-ray visibility than the superelastic section.
- 1 3. The device of claim 1 having a length wherein each of the superelastic
2 section and the plastically deformable section extend longitudinally along the length of the
3 device.
- 1 4. The device of claim 1 further comprising a plurality of filaments
2 including one or more superelastic filaments and one or more plastically deformable
3 filaments.
- 1 5. The device of claim 4 having a length, wherein said one or more
2 superelastic filaments extend longitudinally substantially parallel to said one or more
3 plastically deformable filaments along the length of the stent.
- 1 6. The device of claim 5 having a first end and a second end, wherein
2 each of said superelastic filaments and said plastically deformable filaments extends only
3 once from the first end to the second end of the stent.
- 1 7. The device of claim 4 having a first end and a second end, wherein at
2 least one of said superelastic filaments or deformable filaments longitudinally traverses the
3 length of the stent from the first end to the second end in a plurality of columnar units.
- 1 8. The device of claim 4 consisting of a single superelastic filament and a
2 single plastically deformable filament.
- 1 9. The device of claim 4, wherein each of said superelastic filaments is
2 connected along one or more longitudinal portions thereof to another superelastic filament,
3 another columnar unit of the same superelastic filament, one or more of said plastically
4 deformable filaments, or a combination thereof, and each of said plastically deformable
5 filaments is connected along one or more longitudinal portions thereof to another plastically

6 deformable filament, another columnar unit of the same plastically deformable filament, one
7 or more of said superelastic filaments, or a combination thereof.

1 10. The device of claim 9, wherein the longitudinal portions are connected
2 at a joint by one of: a brazed connection, a weld, an adhesive bond, or a suture.

1 11. The device of claim 9 further comprising one or more joints
2 comprising: a first longitudinal portion of one of the superelastic filaments, a second
3 longitudinal portion of one of the plastically deformable filaments abutting said first portion,
4 and a joining coil wrapped about said first and second portions.

1 12. The device of claim 11, wherein said superelastic filaments comprise a
2 superelastic grade of nitinol; said plastically deformable filaments comprise a material
3 selected from the group consisting of: gold, platinum, tantalum, titanium, stainless steel,
4 tungsten, a nickel alloy, a cobalt alloy, a titanium alloy, and a combination thereof; and said
5 brazed coil comprises a thermal shape memory grade of nitinol.

1 13. The device of claim 1, wherein each said superelastic section comprises
2 a precision-cut sheet or a longitudinally severed precision-cut tube.

1 14. The device of claim 13, wherein each said plastically deformable
2 section comprises at least one columnar unit having a zig-zag configuration disposed between
3 two superelastic sections or between opposite longitudinal edges of a single superelastic
4 section.

1 15. The device of claim 14 consisting of a single plastically deformable
2 section comprises a single columnar unit attached between opposite longitudinal edges of a
3 single superelastic section.

1 16. The device of claim 1, wherein each plastically deformable section
2 comprises a combination of superelastic material and plastically deformable material wherein
3 said plastically deformable material constrains the superelastic material.

1 17. The device of claim 16, wherein said combination is selected from a
2 group consisting of: plastically deformable material plated onto said superelastic material, a
3 plastically deformable hypotube overlaid onto said superelastic material, ion implantation of

4 said plastically deformable material into said superelastic material, and a composite
5 comprising said deformable material and said superelastic material.

1 18. The device of claim 16, wherein the combination comprises a
2 composite comprising plastically deformable material sandwiched between inner and outer
3 layers of superelastic material.

1 19. The device of claim 16, wherein the plastically deformable material is
2 gold.

1 20. The device of claim 16 further comprising one or more hoops in a zig-
2 zag configuration of oppositely-pointing apex sections, each plastically deformable section
3 comprising one or more apex sections comprising said plastically deformable material.

1 21. The device of claim 19 further comprising a plurality of hoops wherein
2 the apex sections pointed in a first direction on each of said hoops are longitudinally aligned
3 and the plastically deformable apex sections on each of said hoops are longitudinally aligned.

1 22. The device of claim 1 having a first constrained diameter, a second
2 fully-self-expanded diameter, and a third fully-forcibly-expanded diameter, wherein said
3 third diameter is greater than said second diameter and said second diameter is greater than
4 said first diameter.

1 23. The device of claim 1, wherein each of said superelastic sections
2 comprises nitinol and each of said plastically deformable sections comprises a plastically
3 deformable material selected from the group consisting of: gold, platinum, tantalum,
4 titanium, stainless steel, tungsten, palladium, a nickel alloy, a titanium alloy, a cobalt alloy,
5 and a combination thereof.

1 24. The device of claim 1, wherein the device is selected from the group
2 consisting of: a stent and a vena cava filter.

1 25. The device of claim 1, wherein said at least one superelastic section
2 comprises a first tubular section and said at least one plastically deformable section comprises
3 a second tubular section.

CONFIDENTIAL

Application No. 09/702226
Filed: October 31, 2000
Inventor: Walak

- 25 -

1 26. The device of claim 25, wherein the first tubular section consists
2 essentially of a superelastic material alone and the second tubular section consists essentially
3 of plastically deformable material alone.

1 27. The device of claim 25, wherein the second tubular section comprises a
2 combination of superelastic material and plastically deformable material having a first ratio of
3 plastically deformable material to superelastic material.

1 28. The device of claim 27, wherein the device comprises two opposite end
2 sections having a middle section therebetween, the middle section comprising the first tubular
3 section, and the two opposite ends each comprising second tubular sections.

1 29. The device of claim 28, wherein each end section comprises the
2 plastically deformable material aligned in longitudinal stripes between stripes of superelastic
3 material.

1 30. The device of claim 27, wherein the first tubular section comprises a
2 combination of superelastic material and plastically deformable material having a second ratio
3 of plastically deformable material to superelastic material less than said first ratio.

1 31. The device of claim 25 further comprising a third tubular section
2 comprising a superelastic section, the second tubular section disposed longitudinally between
3 the first tubular section and the third tubular section, the first tubular section having a first
4 fully-self-expanded diameter and the second tubular section having a second fully-self-
5 expanded diameter.

1 32. The device of claim 31, wherein the first fully-self-expanded diameter
2 is less than the second fully-self-expanded diameter, and the second tubular section has a
3 fully-forcibly-expanded diameter at least as great as said second fully-self-expanded diameter.

1 33. A method of manufacturing an endoluminal device having an
2 architecture, said method comprising:

3 (a) forming a composite comprising a first layer comprising a first
4 material, a second layer comprising the first material, and an intermediate layer between the
5 first and second layers comprising a second material in a non-continuous distribution; and

6 (b) cutting or etching away portions of the composite tube in a pattern to
7 form the device architecture.

1 34. The method of claim 33, wherein step (a) comprises forming the
2 composite as a sheet and rolling the sheet to a desired thickness.

1 35. The method of claim 34 further comprising forming the sheet into a
2 tube prior to step (b).

1 36. The method of claim 34 further comprising forming the device
2 architecture into a tubular shape after step (b).

1 37. The method of claim 33, wherein step (a) comprises forming the
2 composite as tube wherein the first layer is an inner annular layer and the second layer is an
3 outer annular layer and the intermediate layer is an annular layer between the inner and outer
4 layers.

1 38. The method of claim 33 wherein the non-continuous distribution
2 comprises a continuous longitudinal stripe, a non-continuous longitudinal stripe, a continuous
3 transverse stripe, or a non-continuous transverse rings.

1 39. A method of deploying an endoluminal device in a body lumen, the
2 device comprising at least one superelastic section and at least one plastically deformable
3 section, the method comprising:

4 (a) introducing the device into the body lumen with the device radially
5 constrained in a first configuration having a first diameter;

6 (b) allowing the device to self-expand into a second configuration having a
7 second diameter greater than the first diameter and less than or equal to a fully-self-expanded
8 diameter; and optionally,

9 (c) forcibly expanding the device into a third configuration in which at
10 least one longitudinal portion of said device has a third diameter greater than said second
11 diameter and equal to or less than a fully-forcibly-expanded diameter.

CONFIDENTIAL

Application No. 09/702226
Filed: October 31, 2000
Inventor: Walak

- 27 -

1 40. The method of claim 39 wherein step (c) comprises using a balloon to
2 forcibly expand said device into said third configuration.

1 41. The method of claim 40 wherein step (c) further comprises using said
2 balloon to forcibly expand at least portions of said device into a fourth, intermediate
3 configuration having a fourth, overexpanded diameter greater than said fully-forcibly-
4 expanded diameter, and then allowing said device to relax to said third configuration.

1 42. The method of claim 39 wherein the device comprises a first, tubular
2 section comprising one of the superelastic sections and a second tubular section comprising
3 one of the plastically-deformable sections, the first tubular section having a first fully-self-
4 expanded diameter and the second tubular section having a fully-forcibly expanded diameter
5 greater than the first fully-self-expanded diameter, the method further comprising:

6 in step (a) introducing the device into the body lumen with the device radially
7 constrained in the first configuration in which each tubular section has the first diameter;

8 in step (b) allowing the device to self-expand into the second configuration in
9 which the first tubular section has the second diameter; and

10 in step (c) forcibly expanding the device into the third configuration in which
11 the second tubular section has a diameter greater than the second diameter of the first tubular
12 section.

1 43. The method of claim 42, wherein the device is deployed in a lumen
2 comprising a tapered portion, the method further comprising:

3 in step (b) allowing the device to expand in a location wherein the second
4 tubular section is aligned with the tapered portion of the lumen; and

5 in step (c) forcibly expanding said second tubular section to conform to said
6 tapered portion of the lumen such that the second tubular section comprises a variable
7 diameter expanding from essentially the second diameter of the first tubular section at a first
8 end to larger diameter at a second end.

1 44. The method of claim 42, wherein the device has a middle section and
2 two opposite end sections, the first tubular section comprises the middle section, the end

3 sections each comprise second tubular sections, the device is introduced into the body on a
4 balloon catheter, and in step (b) the second configuration comprises a configuration wherein
5 the second tubular sections remain in contact with the balloon catheter.

1 45. The method of claim 42, wherein the device has a middle section and
2 two opposite end sections, the first tubular section comprises the middle section, the end
3 sections each comprise second tubular sections, and the third configuration into which the
4 second tubular section is forcibly expanded in step (c) comprises a configuration wherein one
5 or both end sections are tapered.

6 46. The method of claim 39 wherein the device comprises a first, tubular
7 section comprising one of the superelastic sections, a second tubular section comprising one
8 of the plastically-deformable sections, and a third tubular section comprising one of said
9 superelastic sections, the second tubular section disposed longitudinally between the first
10 tubular section and the third tubular section, the first tubular section having a first fully-self-
11 expanded diameter, the third tubular section having a second fully-self-expanded diameter
12 greater than or equal to the first fully-self-expanded diameter, and the second tubular section
13 having a fully-forcibly expanded diameter at least as great as the second fully-self-expanded
14 diameter, the method further comprising:

1 in step (a) introducing the device into the body lumen with the device radially
2 constrained in the first configuration in which each tubular section has a first diameter;

3 in step (b) allowing the device to self-expand into the second configuration in
4 which the first and third tubular sections each have respective second diameters greater than
5 the respective first diameters and less than or equal to the respective fully-self-expanded
6 diameters; and

7 in step (c) forcibly expanding the device into the third configuration in which
8 the second tubular section has a diameter greater than said second diameter of the first
9 tubular section.

1 47. The method of claim 46 wherein said third tubular section has a greater
2 fully-self-expanded diameter than said first tubular section, and wherein the device is
3 deployed in a lumen comprising a smaller diameter portion, a larger diameter portion greater

CONFIDENTIAL

- 29 -

Application No. 09/702226
Filed: October 31, 2000
Inventor: Walak

4 than said smaller diameter portion, and a tapered portion between said smaller diameter
5 portion and said larger diameter portion, the method further comprising:

6 in step (b) allowing the device to expand in a location wherein the first tubular
7 section is aligned with the smaller diameter portion of the lumen, the second tubular section
8 is aligned with the tapered portion of the lumen, and the third tubular section is aligned with
9 the larger diameter portion of the lumen; and

10 in step (c) forcibly expanding said second tubular section to conform to said
11 tapered portion of the lumen such that the second tubular section comprises a variable
12 diameter ranging from essentially the second diameter of the first tubular section at a first end
13 to essentially the second diameter of the third tubular section at a second end.